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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,171

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Peter Joseph Ayre

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EXAMINER

LAVERT, NICOLE F

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No. 10/588,171	Applicant(s) AYRE ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3** are rejected under 35 U.S.C. 102(b) as being anticipated by Sass (US 2002/0058978).

For **claim 1**, Sass discloses, a percutaneous lead assembly configured to supply electrical signals to a medical device implanted within a body of a patient {[0002] & (Fig 2, 10)}, said lead assembly comprising a flexible elongate member having a first portion adapted to remain external to the body of the patient, said first portion having a first diameter {[0026] & (Fig 1, 60)}; and a second portion joined to said first portion and adapted to extend through a hole in a skin layer of the body of the patient {[0025] & (Fig 1, 50)}, and wherein said second portion has a second diameter which is substantially smaller than said first diameter (Fig 1, 60 & 50).

In regards to **claim 2**, Sass discloses, the percutaneous lead assembly as claimed in claim 1 (Fig 2, 10) wherein said first portion includes a shielding layer {[0026] & (Fig 2, 64)}.

In regards to **claim 3**, Sass discloses, the percutaneous lead assembly as claimed in claim 1 (Fig 2, 10) wherein at least a segment of said second portion is covered with a textured surface {[0025] & (Fig 2, 52)}.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 4** rejected under 35 U.S.C. 103(a) as being unpatentable over Sass (US 2002/0058978) in view of Jarvik (US 5,904,646).

Sass shows all features of the instantly claimed invention as discussed above.

Sass fails to disclose the first and second portions of a lead assembly joined by connectors.

Jarvik et al. teaches a means of bringing electrical power across the skin to an implanted electrical device comprising an internal and an external connector used to connect the cable external to the patient to be connected to the internal cable implanted within the patient [(col 2, ln 22-26)

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sass with the use of the external and internal connectors as taught by Jarvik in order to provide predictable results pertaining to connecting the external and internal leads in a way as to replace or change the external cable non-invasively in event the external cable is damaged (Jarvik, col 2, ln 22-26).

6. **Claims 5** rejected under 35 U.S.C. 103(a) as being unpatentable over Sass (US 2002/0058978) in view of Jarvik (US 5,904,646).

Sass shows all features of the instantly claimed invention as discussed above.

Sass fails to disclose a percutaneous lead assembly including a lead restraint.

Jarvik et al. teaches a means of bringing electrical power across the skin to an implanted electrical device comprising mounting electrical connector in the form of a flange [(col 2, ln 27-34) & (Fig 1, 2)].

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sass with the use of the resistant flange in order to provide predictable results pertaining to providing a robust percutaneous lead assembly resilient to damage in the event of trauma (Jarvik, col 2, ln 31-34).

7. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sass (US 2002/0058978) and Jarvik (US 5,904,646) as applied to claim 5 above, and further in view of Imran et al. (5,449,381).

Sass/Jarvik shows all features of the instantly claimed invention as discussed above.

Sass/Jarvik fails to disclose a flexible, elongated unshielded member that extends through a hole in a skin layer of the body.

Imran et al. teaches a catheter, including a flexible, elongated and tubular member, which is placed beneath the skin and extends to the heart [(col 2, ln 37-42) & (col 4, ln 52-55)].

It would have been obvious to one of ordinary skill at the time of the invention to have modified Sass/Jarvik with the use of the flexible member placed beneath the skin as taught by Imran et al. in order to provide predictable results pertaining to implanting the device so the device can be utilized for electrically stimulating the body and delivering said electrical stimulation such as performing defibrillation and cardioversion of the heart (Imran, col 4, ln 59-63).

Response to Arguments

8. Applicant's arguments with respect to claims 1-5 & 7 have been considered but are moot in view of the new ground(s) of rejection. See the above action.

9. Applicant's arguments, filed 31 March 2008, with respect to objections of the specification and the drawings in addition to the 35 U.S.C 101 rejections of claims 6 & 7 have been fully considered and are persuasive. Therefore, the above objections and 35 U.S.C. 101 rejections of the specification, drawings and claims 6 & 7 have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762